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PATENT
P-3946C1C1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT EXAMINING OPERATION

APPLICANT(S): Robert B. ODELL et al.

SERIAL NO.: 09/897,309 GROUP:

FILING DATE: 07/02/2001 EXAMINER:

FOR: METHOD AND APPARATUS FOR MANUFACTURING, FILLING AND PACKAGING MEDICAL DEVICES AND MEDICAL CONTAINERS

AMENDMENT IN RESPONSE TO NOTICE TO FILE CORRECTED APPLICATION PAPERS

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Notice to File Corrected Application Papers dated 07/31/2001, please amend the above-identified application as follows:

IN THE ABSTRACT

Please substitute the attached Abstract for the previously filed Abstract.

REMARKS

Applicants have reviewed the Notice to File Corrected Application Papers, and in response thereto, Applicants have revised the Abstract and attached a new Abstract on a separate sheet (37 CFR 1.72(b)). An early and favorable action on the merits is respectfully requested.

In addition, attached hereto is a marked-up version of the changes made to the Abstract of the Disclosure by the current amendment. The attached page is captioned **"VERSION WITH MARKINGS TO SHOW CHANGES MADE."**

In the event that any issues remain, an interview is requested with the undersigned attorney of record. In addition, the Commissioner is hereby authorized to charge any fees which may be required in connection herewith or credit any overpayment to Deposit Account No. 02-1666.

Respectfully submitted,

By: _____
Allen W. Wark, Reg. No. 30,503
Attorney for Applicant(s)

Becton, Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417-1880
TEL: (201) 847-7115 (Direct)
FAX: (201) 848-9228 or 847-5377

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Abstract of the Disclosure

[Glass] [m]Medical devices such as medical containers can be formed of glass [are manufactured] and annealed [by heating in an oven] which produces a clean device having a low bio-burden,[. Plastic medical devices and medical containers are] or formed by plastic molding [devices] which produces a clean device. The clean devices are immediately transferred to a controlled environment [to maintain a clean work area. The work area can be a] such as a clean room or localized area to avoid the need to maintain cleanliness levels in an entire room. [A localized area uses a housing assembly having a HEPA filter coupled to an air inlet to filter the air entering the housing. An air blower is coupled to the air inlet to feed filtered air into the housing assembly and to maintain a positive air pressure in the housing assembly to prevent unfiltered outside air from entering.] Syringe tip closures can be introduced into the housing assembly, where syringe barrels and tip closures are cleaned with filtered ionized air and the tip closures are coupled to the barrels. [A thin coating of lubricant is applied to the inner surfaces of the syringe barrels.] The syringe barrels [or medical container] can be filled with a substance and a closure member [is] attached. While still in the housing assembly the syringe barrels can be formed into an array and placed in a clean outer container, which[. The outer container] is then closed and sealed. [The outer container and syringe barrels can be sterilized with heat, radiation or by exposure to a sterilizing gas. The syringe barrels may be prefillable glass or plastic syringe barrels.]